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# From responsible research to responsible innovation: challenges in implementation

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**Abstract:** This study proposes a new approach to the responsible development of innovative products, processes and services by companies and organisations operating in the bioeconomy and related industry sectors. It departs from much of the recent and currently available research on responsible research and innovation in that it recognises the very different challenges faced by innovating organisations, compared to conventional approaches with a strong emphasis on upstream engagement. It attempts to move away from the politicised perspectives that have dominated many engagement initiatives on disruptive innovations like synthetic/engineering biology, and to focus on practical downstream outcomes, the extent to which they will fulfil the aspirations of ordinary citizens, and will comply with prevailing industry norms of responsible behaviour. The proposed consolidated responsible innovation framework builds on the framework developed in 2012 by the then Technology Strategy Board, implemented using the anticipate, reflect, engage and act approach devised by UK research councils. It distinguishes between routine, company-specific aspects of responsibility, expected to be addressed within an organisation's standard operating procedures, and project-specific aspects requiring regular appraisal throughout the development of an innovation. It is designed to be simple and feasible for a company to implement within a commercial environment.

## 1 The concept of responsible research and innovation (RRI)

A common expectation in most societies is that innovation will continue to improve our lives through economic, health-related or environmental benefits [1, 2] and the Organisation for Economic Cooperation and Development sees much of that innovation coming from the bioeconomy – ‘From a broad economic perspective, the bioeconomy refers to the set of economic activities relating to the invention, development, production and use of biological products and processes. If it continues on course, the bioeconomy could make major socioeconomic contributions ... to improve health outcomes, boost the productivity of agriculture and industrial processes, and enhance environmental sustainability.’ [3]. The current scale of the UK bioeconomy was estimated in 2015 to be at least £150 billion gross value added (GVA), supporting ~600 K jobs, and potentially increasing GVA by a further £40 billion over the coming decade [4], and synthetic biology is expected to transform the sustainability and productivity of the industries that contribute to the bioeconomy [5].

There are some potential barriers to the delivery of these expected benefits. There is considerable variation, nationally and societally, in the ways we perceive the risks and benefits of innovative technologies, and the governance processes we put in place for an innovative technology area will determine not just which products and processes are developed but also what scale of company can participate in their development and ultimately the competitive advantage of nations and regions [6]. With this in mind, RRI is being promoted as an essential component of future European Union (EU) governance processes, with a focus on synthetic biology as a leading example, through an extensive and long-running programme of academic research funding initiatives, the assumption being that RRI will be a key component of future EU governance processes and hence to delivering societal acceptance of these technologies.

The European Commissioner for Research Innovation and Science, Maire Geoghegan-Quinn, in 2012 described RRI as contributing to the Europe 2020 Strategy on the creation of

‘a smarter, greener economy where our prosperity will come from research and innovation ... [and] research and innovation must respond to the needs and ambitions of society, reflect its values and be responsible’ [7]. The key areas of RRI are described as: (i) engagement, (ii) gender equality, (iii) science education, (iv) open access, (v) ethics and (vi) governance.

In this paper, we analyse the background and context for development of RRI in the EU, current approaches to the conduct of responsible research (RR) with its focus on upstream engagement, and the need now to translate that to a workable approach to responsible innovation (RI). It will propose new approaches to taking forward legitimate public expectations for responsible behaviour by companies and innovators in the development of new technologies in a way that encourages equitable representation of the views and interests of all relevant stakeholders, and also provides a route to verifiable delivery of RI in practice.

## 2 RRI and its origins

### 2.1 The ELSA agenda and the emphasis on upstream engagement

The antecedents of RRI lie in an earlier research initiative that focused on ethical, legal and social aspects of new technologies (ELSA), from 1994 in the 4th EU Framework Programme [8]. So-called upstream engagement, starting from engaging about early decision making on basic research funding, was seen as the best option to avoid future societal conflicts over life science research and its applications [9]. Research funded under the ELSA agenda and led by academics in the science and technology studies discipline has played an important role both in framing public responses to genetic modification and other innovative technologies and in channelling public responses to these technologies into government decision making on science funding and the development of EU regulatory systems [10–13].

An important event in enabling the policy influence of ELSA research in the UK was the launching by the think tank Demos of the booklet ‘see through science: why public engagement needs to move upstream’ [14] the front cover of which made clear its political ambitions – ‘the task is to make *visible* the invisible, to expose to public scrutiny the assumptions, values and visions that drive science’, and which on p24 suggested that its logical conclusion was ‘... not only [to] change the relationship between science and public decision making but also *the very foundations of knowledge on which science rests*’ (our emphasis). In the periods leading up to and beyond the launch of the Demos booklet, social science research on innovation-related questions in the UK and the EU was heavily dominated by this ELSA agenda.

Despite this overt challenge to the scientific ethos, scientists and science funders embraced upstream engagement on the basis that it would, if managed properly, improve public acceptance of new technologies and would not bring an end to any area of research [15]. However, although upstream engagement has been widely undertaken, for example by UK research councils [16, 17], there is not yet any evidence that better public acceptance of new innovative technologies will result from such engagement [18] and in practice there have been reductions in funding for some areas of science, particularly in nanotechnology [19, 20] and plant biotechnology, arising from political and policy concerns about negative public opinion rather than evidence of potential or actual harm arising from the innovations concerned. Such considerations have also influenced the extent to which genetically modified crops are being cultivated in Europe [21].

The further upstream the engagement, the more remote and uncertain the future innovative products, process or services will be from the needs and concerns of citizens, and in such circumstances citizens are more likely to engage with an issue on the basis of values or ideology rather than local or personal interests [22, 23]. In such cases, conflict and polarisation of views are more likely to arise and resolution of any conflict will be more difficult to achieve [24]. In essence, the more developed a particular novel application towards its end purpose, the more deliberative and meaningful the conversation is likely to be. When citizens are unfamiliar with the issues at stake, engagement — whether upstream or downstream — can become a process of framing these unfamiliar developments, either favourably or unfavourably, in the public mind, potentially giving considerable power to those who conduct the engagement [14]. Table 1 outlines some of the potential problems with engagement at the ‘upstream’ stage of research on an innovative technology.

## 2.2 RRI as part of European research and innovation agendas

The shift from ELSA to RRI in EU funding initiatives has been described by Zwart *et al.* as ‘a new initiative in the labelling arena’, reflecting a shift in emphasis on the part of research funders towards ‘collaboration with industry and potential socioeconomic benefits of scientific and technological change’ [8]. Zwart *et al.* note in the conclusion of their paper that, although RRI was presented as a new approach fostering closer links with innovation processes, it has yet to be articulated by its proponents in a way that clearly distinguishes it from ELSA, observing that achieving the shift of emphasis desired by the funders will require collaboration with a broader range of academic disciplines, including management and innovation studies where researchers have an understanding of how innovations come about, how they are managed and how policy affects them.

Until recently RRI researchers have focused their attention almost entirely on basic science and research and on upstream engagement as means to deliver the responsible behaviour that citizens are presumed to demand [14]. Initiatives in the Framework 7 research programme, most receiving more than a million Euros, included Governance for Responsible Innovation, Res-AGoR, ProGRess, Responsibility, Synnergene and Rising pan-European and International Awareness of Biometrics and Security Ethics.

**Table 1** Problems with upstream stakeholder engagement (adapted from [13])

Group think	The views of small groups, e.g. focus groups, are easily swayed by participants with strong opinions or by those leading the engagement
Issue framing	Given our ignorance about the future, upstream engagement can be a process of fictitiously framing new science and technology in the minds of the public
Recruitment bias	It is difficult to persuade uncommitted citizens to participate in hypothetical discussions about future science and innovation — recruitment is likely to be biased towards those who have a specific agenda
Consensus and conflict	Even in a small group discussion there is unlikely to be agreement on any issue related to innovative technologies, and where there is polarisation of views, upstream engagement can lead to increased levels of conflict and more extreme polarisation
Engagement focus	Some topics, for example nanotechnology or synthetic biology, are too broad and multifaceted to allow meaningful engagement, particularly at the upstream stage
Engagement fatigue	There will be insufficient time and resources to engage on every relevant issue and people will become cynical about the process
Labile public opinion	Most people who do not already have strong opinions will change their minds over relatively short timescales, and much more so over the 10–15 years that will elapse before a disruptively innovative research initiative delivers tangible outcomes in a market place

The Horizon 2020 research programme in 2015, including only those calls with RRI in the title, had 21.8 M Euros of funding available [25] and the latest call under the ‘Science with and for Society’ heading has allocated over 42 M Euros for 14 RRI-related projects [26], with a much stronger focus on industry taking a leadership role than previous funding rounds.

## 2.3 The politicised nature of RRI initiatives

A recent RRI publication [27] comments on a group of scientists (Drew Endy, Jay Keasling, Dick Kitney, Paul Freemont and J. Craig Venter) as ‘high-profile techno-visionaries and political actors ... who have been most successful in securing funding for synthetic biology, publishing in high-profile papers, gaining international prestige and exerting considerable, even disproportionate influence’. However, from the launch of the Demos publication on upstream engagement [14] to the academic discourse on RRI, this political bias in a different direction is present but is rarely commented on – the lead commentators on RRI could be described as high-profile ‘socio-visionaries’ and political actors with similar attributes.

Kuntz [28] has criticised ‘... the worrying ideological shift towards postmodernism which aims to deconstruct Enlightenment values’ and describes the ‘democratisation of science’ as a socially coercive tool for the political control of science [29], and an exchange of correspondence in *Nature* [30–32] demonstrates the contrast in positions of scientists and social scientists around such issues. Contributing to a sense of distrust in the RI process by innovating organisations and companies, the tone of some recommended lines of questioning seems to presume that some things that are publicly unacceptable would otherwise remain hidden, and to suggest an open-ended process that may never reach a conclusion: why are researchers doing it, are these motivations transparent and in the public interest, what do not we know about and what might we never know about? [27].

Politicisation from a range of different perspectives is not uncommon in debates and analyses of issues related to science and innovation, particularly where the innovation is potentially disruptive, and the perception of politicisation can affect the willingness of stakeholders to participate in an engagement initiative, as was the case in early attempts by technology strategy board (TSB) to engage industry actors in RRI processes in the UK. However, reinforcing a political or ideological debate which

is only of interest to a minority of the population will be unhelpful in moving forward with a workable approach to encouraging responsibility in research and innovation. The interests of the majority of citizens will probably be best served by an approach that attempts to maintain an equitable balance across the broad range of values and interests likely to be found in any representative sample of citizens.

### 3 Demonstrating responsible innovation – a consolidated RI framework (CRIF)

To add to the political complexity noted above, most of the research papers on RRI, including most of the contributions to the *Journal of Responsible Innovation*, have been about RR and not RI. There is a clear need now to move beyond the focus on the research community and to consider the very different issues faced in more downstream innovation processes, the different sets of actors and stakeholders that will need to be involved and the need to make decisions on timescales that reflect the real challenges faced by companies in a competitive economic environment. A first attempt to consider the specific needs of innovators was the development in 2012 of a responsible innovation framework (RIF) by the TSB (now innovate UK) [33]. The CRIF described in this paper builds on experience of involvement with implementation of the TSB RIF and attempts to simplify it and develop it further for use by synthetic biology/engineering biology companies. The proposed consolidated framework also incorporates guidance produced by UK research councils led by the Engineering and Physical Sciences Research Council (EPSRC) [34], the anticipate, reflect, engage and act (AREA) approach which, although addressing mainly the behaviour of researchers, can also be adopted to guide the behaviour of innovators at later stages in the development of products, processes or services.

The TSB RIF aimed ‘... to fund projects where the ‘anticipated commercial use’ of the project outcomes meets, on the balance of positive and negative drivers, the standards outlined ‘... for responsible innovation’, and ‘... to help companies *anticipate and give responsible consideration* to the *intended and potential unintended* impacts of the commercial development and use of the technology, including the potential for misuse, *before the work begins*’ (TSB emphases) [33]. It was directed to the activities of companies at all stages in the innovation process, from new spin-out companies to multinational corporations. In developing the RIF, the TSB was faced with the general lack of understanding on how the concept of ‘responsibility’ could best be applied in the context of innovation and built heavily on the standards for corporate social responsibility adopted by large companies, particularly in the financial sector.

The TSB RIF is based on consideration of (i) positive drivers (factors in favour of supporting projects), (ii) negative drivers (factors against supporting projects) and (iii) regulatory drivers, as described in more detail below. Applicants for funding were required to demonstrate that they met these requirements. The consolidated framework proposed here is based on these two UK initiatives: EPSRC AREA approach and TSB RIF. It is seen as potentially more appropriate to the innovation context than most RRI initiatives so far proposed. The starting point for developing the consolidated framework was to separate the requirements specified in the TSB RIF into routine aspects and project-specific aspects as described below.

#### 3.1 Routine aspects of RI compliance

The TSB RIF drivers in Table 2 can be seen as routine in nature, specific to the company or organisation developing the innovation, to be dealt with as part of the pre-award project evaluation process. They include one ‘positive driver’ and seven ‘negative drivers’ and it is clear that the distinction in this list and in Table 3 between positive and negative drivers is a semantic one – any driver could be worded positively (‘organisations that promote sound practices’ will be eligible for funding) or negatively (‘organisations that do not have clear policies on bribery and corruption’ will not be eligible for funding).

Organisations applying for funding would be expected to have policies already in place to deal with these ‘routine’ drivers and any deficiency would lead to rejection of a proposal or at least postponement of funding until the issue is addressed. Once a project is approved for funding ongoing monitoring would be a matter of routine surveillance through the organisation’s standard operating procedures and the EPSRC AREA requirements will not be relevant to these ‘routine’ aspects of implementation of RI.

#### 3.2 Project-specific aspects of RI compliance

The project-specific elements of RI from the TSB RIF, included in Table 3, relate to properties of the innovation itself rather than attributes of the company or organisation and they will vary across projects, including different projects conducted by the same organisation. They may require action during the conduct of a project, should be considered on an ongoing basis and are likely to require more than routine monitoring as the project progresses, potentially also requiring adaptation of the original plans.

The elements of the AREA Framework (7–10 in Table 3) are different in character from those that are incorporated in the TSB RIF (1–6 in Table 3). They describe actions to be undertaken by an organisation to deliver the requirements outlined in elements 1–6 and their role is elaborated below in the context of Table 4.

**Table 2** Routine, company-specific RI elements related to standard business practice

Positive and negative drivers		Criteria
1.	Promoting sound practices in employment, business behaviour and ethics	Organisations should encourage principles of good business behaviour and ethics, including responsible sourcing, fairness, human rights, privacy, the avoidance of child or coerced labour, and accountable governance
2.	Absence of clear policies and procedures on bribery and corruption	Organisations should have appropriate policies in place, including guidance for employees
3.	Inappropriate use of human or animal products and substitutes	Partners should commit to adopting the appropriate codes and regulations
4.	Testing products on animals	Testing on animals should be kept to a minimum and should comply with home office guidelines
5.	Business in countries that violate the political and civil rights of their people	Where the market or components of the supply chain involve countries rated poorly in these respects, the organisations concerned should have effective policies on human rights
6.	Production or sale of weapons	Deriving revenues from this source outwith international treaties and/or for non-defence purposes is discouraged
7.	Addictive substances and behaviours	Projects leading to these outcomes are discouraged
8.	Familiarity and compliance with existing regulations relevant to the project	Organisations convicted of an offence within the last 3 years are not eligible for funding; organisations should demonstrate that they are familiar, and comply, with relevant regulations



**Table 3** Project-specific elements of RI requiring active consideration and monitoring as a project evolves

Source	Element
TSB RIF positive drivers (factors in favour of supporting projects)	1. Products and services that benefit society and/or human well-being 2. Making a positive contribution to the environment 3. Promoting sound practices in employment, business behaviour and ethics
TSB RIF negative drivers (factors against supporting projects)	4. End uses leading to social damage 5. End uses leading to environmental damage or pollution
TSB RIF regulatory driver	6. Regular reassessment of regulatory requirements and implementation of any necessary regulatory changes
EPSRC AREA elements	7. Anticipate – describing/analysing potential impacts relevant to the project 8. Reflect – on purposes of, motivations for and potential implications of the project and associated uncertainties 9. Engage – opening up visions, impacts and questioning to broader deliberation and dialogue 10. Act – using the above processes to influence the direction and trajectory of the research and innovation process.

The semantic distinction between positive and negative drivers is also evident in elements 1–6. Given research showing that, from the perspectives of both regulators and the organisations being regulated, incentives work better than disincentives [35] (compare elements 4 and 1 and elements 5 and 2 in Table 3), we have reworded these issues as positive elements in our consolidated RI framework. This could help to facilitate compliance with RI-related expectations of companies and organisations and reinforce positive public expectations of organisational behaviour. For these reasons, in developing this consolidated framework for RI, negative drivers have been reworded to indicate a positive inducement for organisations to behave in the expected manner. This approach also allows simplification and consolidation of RI-related requirements.

### 3.3 Proposed CRIF

The CRIF brings together the elements of the TSB RIF and the Research Councils' AREA approach, as an interim measure to enable delivery of RI from a perspective that takes account of the needs of innovators as well as meeting societal expectations. It can be seen as a baseline on which new initiatives could usefully build. It focuses on a project-specific set of societal, environmental and regulatory elements, using the AREA elements to guide the RI compliance process. It assumes that routine drivers of an RIF (Section 3.1) will be addressed as part of a company's standard operating procedures and focuses on the project-specific elements (Section 3.2) that will be monitored regularly throughout the development of a new product, process or service, given the

changes likely to emerge over time in the nature of the innovation itself, its expected market and the applicable regulatory systems. The consolidated framework aggregates the drivers of the TSB RIF into societal, environmental, business and regulatory elements (Table 4).

The societal element incorporates elements 1 and 4 of Table 3 as a single positive requirement, adapting the language in the TSB RIF document to remove ambiguities and to focus on the kinds of issues likely to be relevant to an innovating organisation, rephrasing the negative language of element 4. Some initiatives will include both societal and environmental elements but any single project will not necessarily include both.

Where appropriate, the organisation will: develop products, processes or services designed to deliver societal benefits that are life-saving and life-enhancing or contribute to other societal needs, including education, arts, housing, and employment; minimising risks and supporting equitable distribution of risks and societal and economic benefits; protecting human dignity; and avoiding misuse or deliberate harm.

The environmental element similarly incorporates elements 2 and 5 of Table 3.

Where appropriate, the organisation will develop products, processes or services that enhance and support the environment, for example through green transport, waste minimisation, improved efficiency of water use and resilience of water systems, conservation of non-renewable resources, increased use of renewable resources, and considering lifecycle impacts including second and third order effects; ensuring that end uses or processes lead to a net reduction in environmental damage or pollution.

Some aspects of element 3 in Table 3 are captured as routine elements in Table 2: Item 1 (encouraging principles of good business behaviour and ethics; having clear evidence of excellent health and safety systems and a good track record of health and safety issues). The business practice element in Table 3 relates to issues that will require more active project-specific surveillance, for example where new organisations and/or collaborators become involved during development of a product, process or service.

Good business practices should be observed by the organisation *and any associates involved in a project* in responsible sourcing, fairness, human rights, privacy, the avoidance of child or coerced labour and accountable governance.

The regulatory element (element 6 in Table 3) goes beyond compliance with existing regulations that would be captured as a routine element. In areas such as synthetic biology/engineering biology, where regulatory systems are in a state of flux, there is a need to monitor actively the regulatory environment to ensure awareness of changes that may affect an organisation's future activities.

Organisations should commit to regular reassessment of regulatory requirements as the project develops and to implementing any relevant regulatory changes.

Table 4 outlines the proposed consolidated RI framework, incorporating the AREA elements to guide and capture responses to the four CRIF elements: it is the responsibility of the

**Table 4** Consolidated RI framework

Elements of RI	Issues arising during the project	Organisation responses			
		Anticipate	Reflect	Engage	Act
societal element					
environmental element					
business practice element					
regulatory element					

organisation to *anticipate* emerging potential issues throughout conduct of the project. On *reflection*, some will require *engagement* and/or *action*, but others will not, so it is not appropriate to expect every box in this matrix to be addressed to demonstrate responsibility. The CRIF is an attempt to clarify and simplify the process of compliance with RI requirements in the context of innovative biotechnologies such as synthetic biology/engineering biology. It will be relevant to both small and large companies and research institutes as they move from basic research in these areas to the development of products, processes and services.

## 4 Conclusions and future developments in RI compliance by companies and organisations

There has been little coordination across organisations tasked with implementing an RI approach, and no consensus around what should constitute such an approach. As currently being implemented, 'responsible behaviour' requires scientists and innovators to undertake effective public engagement about planned research and future innovative developments and then to adapt them where necessary to comply with the development of '... harmonious models for responsible research and innovation that integrate public engagement, gender equality, science education, open access and ethics' [7]. The absence of any reference to innovation or the societal benefits it may be able to deliver are notable, as is the assumption that there will be a societal consensus on which to base such policies.

What is lacking is a means to move beyond current RR initiatives and develop an approach to RI that transcends current academic disciplinary structures and is based on an understanding of innovation processes and strategies in different technology sectors. Success in this initiative will depend on demonstrating that any suggested approach will not incorporate covert politicisation in any direction, as discussed in Section 2.3. The CRIF (Section 3.3) proposes a basic framework that (i) could be adapted for future innovative developments in a broad spectrum of innovative technologies, (ii) could satisfy a broad spectrum of societal needs and desires and (iii) does not unnecessarily delay or inhibit commercialisation of products, processes or services.

In future RI-related initiatives, the relevant industry sectors will have an important proactive role to play in their development, but this process has not yet begun in any formal sense. It is also notable that, throughout all discussions and recommendations on RR and RI, the focus has been entirely on the need for scientists and innovators to behave responsibly. Based on the ethical principle of equitable treatment of all stakeholders, the field is open for new approaches to RR and RI that also include the desirability of responsible behaviour by stakeholders and citizens (in engaging 'responsibly' with other stakeholders) [13], as currently being considered in a project funded by the British Standards Institution [36].

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